

510 (K) Summary

JUN 16 2009

**SUMMARY OF SAFETY AND EFFECTIVENESS FOR
EZvue (Ocufileon D) Soft (hydrophilic) Contact Lens for Daily Wear****Submitter Information:**

Company: **I-SEE VISION TECHNOLOGY INC.**
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30071
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Identification of Device:

Classification Name: Soft hydrophilic contact lens, per 21 CFR. 886.5925
Trade Name: EZvue (Ocufileon D) Soft (hydrophilic) Contact Lens for
Daily Wear
Common or usual Name: Soft (hydrophilic) Contact lens (daily wear)
FDA Classification: Class II

Predicate Device:

Hydron Biomedics 55 (Ocufileon D) Visibility Tint Molded daily wear soft contact lens
cleared via K972303 Ocular Sciences / American Hydron Inc.

Indications for Use

EZvue (Ocufileon D) Soft (hydrophilic) Contact Lens for Daily Wear is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or not-aphakic persons with non-diseased eyes who may exhibit refractive astigmatism up to 2.00 diopters that does not interfere with visual acuity..

Eye care practitioners may prescribe the contact lens for frequent replacement wear, with cleaning, rinsing and disinfection and scheduled replacement **as prescribed by the eyecare professional**. The contact lens may be disinfected using chemical (not heat) disinfection system.

Description of Device

EZvue (Ocufileon D) Soft (hydrophilic) Contact Lens for Daily Wear are available as spherical lenses manufactured by cast molded method. The lens is made from a lens material that is approximately 55% water. The hydrogel lens' material is a

copolymer composed of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid (MAA), which was cross-linked with Ethylene Glycol Dimethacrylate (EGDMA) via UV photo-polymerization. The EZvue (Ocufilecon D) lens with visible tint is tinted blue using Reactive Blue Dye #19 to make the lens more visible for handling. Lenses are supplied sterile in sealed blister packs containing sterile isotonic phosphate buffered saline.

Summary of Clinical Study:

The EZvue (Ocufilecon D) Soft (hydrophilic) Contact Lens for Daily Wear were tested in 64 human eyes separately within 6 months. Nearly a hundred percent of the participants' vision was corrected and nearly all were satisfied with the lens wearing and care of lenses. In general, these products are good and safe for customers.

Nonclinical Studies:

A series of nonclinical performance tests were performed to demonstrate the safety and effectiveness of the EZvue (Ocufilecon D) Soft (hydrophilic) Contact Lens for Daily Wear, and establish substantial equivalence to predicate lenses - Hydron Biomedics 55 (Ocufilecon D) Visibility Tint Molded daily wear soft contact lens (K972303). All testing was conducted in accordance with the May 1994 FDA guideline titled *Premarket Notification 510(K) Guidance Document for Class IV Contact lenses*, and in conformance to applicable device regulations. The evidence of substantial equivalent to the predicate lens described as follow:

a) Technological characteristics studies

EZvue (Ocufilecon D) Soft (hydrophilic) Contact Lens for Daily Wear designs in the following parameter ranges:

Diameter range: 13.80~14.40mm

Power range: +8.00D~-12.00D

Center thickness: varies with power (0.080~0.150mm)

Lenses have the following properties:

Refractive index: 1.410 (hydrated)

Light transmittance: >93%

Water content: 54 to 56 %

Oxygen permeability (edged corrected): $16 \times 10^{-11} [(\text{cm}^2/\text{sec})(\text{mlO}_2/\text{ml-mmHg})] @ 35^\circ\text{C}$

There characterizations of EZvue (Ocufilecon D) Soft (hydrophilic) Contact Lens for Daily Wear s are equivalent and comparable to those of predicate lenses.

b) Biocompatibility

In accordance with the May 1994 Guidance Document for daily wear contact lenses, toxicity studies have been conducted on the model: EZvue (Ocufilecon D) Soft

(hydrophilic) Contact Lens for Daily Wear. The Irritation test in the rabbit eye and Systemic toxicity studies indicate the extracts would be considered as non-toxic and nor irritated. The Cytotoxicity testing demonstrates the lens is not cytotoxic under the conditions of the study.

c) Microbiology

Steam sterilization process has been validated to deliver a minimum SAL of 10^{-6} , thereby complying with the requirement of FDA Group IV. There is shelf-life stability data supporting that the lens remains sterile through the expiration date claimed for the product.

d) Leachability

Studies were conducted to determine the leachable materials from the finished lens. The results show that, at the levels of the detection reported, there are no leachable monomers and additive residues.

Substantial equivalence Statement:

Testing performed on the EZvue (Ocufileon D) Soft (hydrophilic) Contact Lens for Daily Wear indicated that it can support the efficiency and security use as well as the predicate devices- Hydron Biomedics 55 (Ocufileon D) Visibility Tint Molded daily wear soft contact lens (K972303), when used in accordance with the instructions for use. It is due to the facts that The risks and benefits of the subject device are the same as soft contact lenses for to the daily wear.

In conclusion, it is I-SEE's conviction that data submitted in this 510(k) to validate the claim of substantial equivalency, substantiates our ability to manufacture a soft contact lens, the EZvue (Ocufileon D) Soft (hydrophilic) Contact Lens for Daily Wear, with the same established safety profile and effectiveness as the predicate device-- Hydron Biomedics 55 (Ocufileon D) Visibility Tint Molded daily wear soft contact lens (K972303).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

I-See Vision Technology Inc.
c/o Ms. Jennifer Reich
Senior Consultant
Harvest Consulting Corp.
2904 N. Boldt Drive
Flagstaff, AZ 86001

JUN 16 2009

Re: K082879

Trade/Device Name: EZvue (Ocufilecon D) Soft (hydrophilic) Contact Lens for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lenses
Regulatory Class: Class II
Product Code: LPL
Dated: June 9, 2009
Received: June 11, 2009

Dear Ms. Reich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Malvina B. Eydelman".

Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic, Neurological and

Ear, Nose and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082879

Device Name: EZvue (Ocufileon D) Soft (hydrophilic) Contact Lens for Daily Wear
I-SEE Vision Technnology Inc.

Indications For Use:

EZvue (Ocufileon D) Soft (hydrophilic) Contact Lens for Daily Wear is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or not-aphakic persons with non-diseased eyes who may exhibited refractive astigmatism up to 2.00 diopters that does not interfere with visual acuity..

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Prescription Use V
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Ophthalmic and Ear,
Nose and Throat Devices

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